SEP 2 1 2005

K051988

Superior Products, Inc.
3786 Ridge Road Cleveland, Ohio 44144
(216) 651-9400 / FAX (216) 651-4071

510(k) SUMMARY

1. **Submitter Information:**

Superior Products, Inc.
3786 Ridge Rd.
Cleveland, Ohio 44144

Contact Person: Ronald Johnston
Phone 216-651-9400
Fax 216-651-4071

2. **Date Prepared**: June 1, 2005

3. **Name of Device:**

Trade Name: Oxy-Serve II Oxygen Conserving Regulator
Common Name: Oxygen Conserver
Classification Name: Non-continuous ventilator (IPPB), 21 CFR 868.5905
Regulatory Class: II (two)
Product Code: NFB

4. **Predicate Device Information:**

1. **K010747** - OPC Oxygen Conserving Regulator - Western Medica, Corp.

5. **Device Description:**

The Oxy-Serve II Oxygen Conserving Regulator is a high pressure oxygen regulator integrated with a conserving device to deliver oxygen during the inhalation phase of a patients breathing cycle, thereby extending the useful life of an oxygen cylinder.

The Oxy-Serve II is constructed of aluminum with brass high pressure chamber components. The device is pneumatic and requires no electrical power source. An indexable control knob selects from 11 flow rates ranging from 1 to 6 LPM in .5 LPM increments. Two outlet ports are connectable using a dual lumen cannula. One port senses the inhalation of the patient thus initiating the selected flow to the patient during the full inhalation cycle. Flow ceases at the end of the inhalation cycle. The second port delivers the oxygen.

The device can operate as a conserving regulator, or as a standard continuous flow regulator operable by sliding a switch on the face of the regulator housing. In continuous mode the sensing diaphragm control component is bypassed and a continuous flow of oxygen is delivered at the flow selected by the indexable control knob through the outlet port.

6. **Indications for Use:**

The Oxy-Serve II Oxygen Conserving Regulator is intended as an oxygen conserving pressure regulator for ambulatory patients. The Conserving Regulator delivers a prescribed flow of oxygen only during the inhalation cycle, conserving oxygen during the exhalation cycle.

7. **Intended Use:**

The Oxy-Serve II Oxygen Conserving Regulator is intended to be used in home, respiratory, pulmonary, and skilled care facilities by ambulatory patients who have been diagnosed as requiring and have been prescribed oxygen administration by a physician. The Conserver is used in conjunction with portable oxygen cylinders to extend the usable cylinder life by delivering oxygen only during the inhalation portion of the patients breathing cycle.

8. **Substantial Equivalence:**

The Oxy-Serve II Oxygen Conserving Regulator is substantially equivalent to K010747 - OPC Oxygen Conserving Regulator - Western Medica. The device has the same technological characteristics (i.e., materials, energy source, mode of operation) as the predicate device and functions similarly through the use of a pressure reducing regulator and flow sensing diaphragms to control the delivery of the oxygen.

9. **Performance Testing:**

The Oxy-Serve II Oxygen Conserving Regulator has been subjected to performance, mechanical, and environmental testing to insure the device meets the performance criteria as intended.

10. **Conclusions:**

The Oxy-Serve II Oxygen Conserving Regulator, having the same intended use as the predicate device, and having been proven through lab testing to have similar performance characteristics, as well as passing extensive safety testing, is substantially equivalent to the legally marketed predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2005

Mr. Ronald Johnson
Director of Engineering
Superior Products, Incorporated
3786 Ridge Road
Cleveland, Ohio 44144

Re: K051988
Trade/Device Name: Oxy-Serve II Oxygen Conserving Regulator
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-Continuous Ventilator (IPPB)
Regulatory Class: II
Product Code: NFB
Dated: September 12, 2005
Received: September 13, 2005

Dear Mr. Johnston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

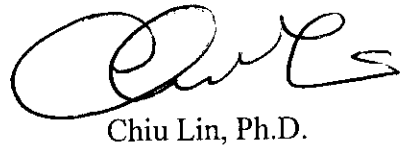
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051988

Device Name: Oxy-Serve II Oxygen Conserving Regulator

Indications For Use:

The Oxy-Serve II Oxygen Conserving Regulator is intended as an oxygen conserving pressure regulator for ambulatory patients. The Conserving Regulator delivers a prescribed flow of oxygen only during the inhalation cycle, conserving oxygen during the exhalation cycle.

Prescription Use X (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number K051988